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6 October 2021

Simon Brown

By email: fyi-request-16608-21509624@requests.fyi.org.nz
Ref: H202111774

Dear Simon

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) on 3 September 2021 for information regarding Pfizer clinical trials.

You specifically requested:

> *"any and all minutes taken of meetings held by Medsafe pertaining to efficacy and clinical safety issues surrounding the Pfizer clinical trials of BNT162b2 mRNA COVID-19 Vaccine. I am specifically interested in Medsafe's independent analysis and appraisal of the above mentioned trials.*
>
> *I would also like copies of any and all correspondence between Medsafe and the COVID Vaccine Technical Advisory Group pertaining to any and all safety concerns regarding BNT162b2. These concerns include but are not necessarily restricted to the clinical trial design; the exclusion of subjects from both the placebo and treated groups in the analysis of published data (N Engl J Med. 2020; 383: 2603-2615; FDA website); the use of disease-specific endpoints instead of "all cause mortality and morbidity"; and what advice was given."*

The Ministry of Health (the Ministry) has identified three documents in scope of your request. These are outlined in Appendix 1 of this letter, with copies enclosed. Where information is withheld, this is noted in the Appendix and in the document itself.

Under section 28(3) of the Act you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: info@ombudsman.parliament.nz or by calling 0800 802 602.

Please note that this response, with your personal details removed, may be published on the Ministry website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Yours sincerely

Chris James
Group Manager
Medsafe

Appendix 1: List of documents for release

#	Date	Document details	Decision on release
1	January 2021	New Medicine Application Evaluation Report – Clinical	Released with some information withheld under the following sections of the Act: • section 9(2)(b)(ii) where its release would likely unreasonably prejudice the commercial position of the person who supplied the information; and • section 9(2)(g)(ii) to protect Ministers, members of organisations, officers, and employees from improper pressure or harassment.
2	20 January 2021	Science and Technical Advisory Team – Request for Information	Released with some information withheld under section 9(2)(g)(ii) of the Act.
3	3 February 2021	Medicines Assessment Advisory Committee minutes and recommendations - 109th meeting on 2 February 2021	Released with some information withheld under the following sections of the Act: • section 9(2)(a) to protect the privacy of natural persons; and • section 9(2)(g)(ii).